

## REMARKS

### I. Status

Claims 58 and 62-90 are pending. Claim 67 has been amended to correct a typographical error. There is no issue of new matter.

### II. Double Patenting

1. Claims 58 and 62-90 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 and 41-46 of copending Application No. 11/793,473.

Pursuant to MPEP 804 I(B)1, if a provisional nonstatutory obviousness-type double patenting rejection is the only rejection remaining in the earlier filed of the two pending applications, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer.

Applicants submit that the instant application, which was filed on June 16, 2004, was filed earlier than the '473 Application, which was filed as a national stage application of PCT/US2005/046983 filed on December 20, 2005. Therefore, Applicants will not address the merit of the provisional obviousness double patenting rejection but request that the Office permit the subject application to issue without a terminal disclaimer upon withdrawal of other rejections.

2. Claims 58 and 62-90 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 11/599,050. Applicants traverse this rejection.

The pending claims are directed to a **hydrochloric acid salt** of (R)-8-chloro-1-methyl-2,3,4,5-tetrahydro-1*H*-3-benzazepine, solvates or hydrates thereof, compositions thereof, and methods of use therefore. The pending claims of the '050 application are directed to a **pharmaceutically acceptable salt** of (R)-8-chloro-1-methyl-2,3,4,5-tetrahydro-1*H*-3-benzazepine, solvates or hydrates thereof, compositions thereof, and methods of use therefore. Applicants

submit that the claims of the '050 application do not provide any teaching, suggestion or direction for a person skilled in the art to choose that particular hydrochloric acid salt among the many possible pharmaceutically acceptable salts. Therefore, the pending claims are not obvious in view of the pending claims of the '050 application. Withdrawal of the rejection is respectfully requested.

### **III. 35 U.S.C. § 112, First Paragraph**

Claims 67 and 72-90 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for salt forms, allegedly does not reasonably provide enablement for solvates and hydrates. Applicants respectfully disagree.

Applicants submit that the hydrochloric acid salt of (R)-8-chloro-1-methyl-2,3,4,5-tetrahydro-1*H*-3-benzazepine possesses the property of readily forming solvates, including hydrates. Applicants refer the Office to WO 2006/069363 (page 16, Example 2), which discloses the preparation of a hemihydrate of a hydrochloric acid salt of the compound (R)-8-chloro-1-methyl-2,3,4,5-tetrahydro-1*H*-3-benzazepine. Specifically, that PCT publication reports that the compound 8-chloro-1-methyl-2,3,4,5-tetrahydro-1*H*-benzazepine hydrochloride is treated with water and cyclohexane, followed by cooling, to yield the hemihydrate of the salt. Hence, a hydrate of the hydrochloric acid salt exists.

Applicants also refer the Office to WO 2007/120517 (pages 27-29, Example 4), which shows that an anhydrous hemitartrate salt of 8-chloro-1-methyl-2,3,4,5-tetrahydro-1*H*-benzazepine is converted to a hemihydrate hydrochloric acid salt with a water content of about 3.7% by weight. That also demonstrates that a hydrate of a salt exists.

Finally, Applicants note that the Board of Patent Appeals and Interferences has repeatedly recognized that *claims to solvates are indeed patentable, even in the absence of working examples*. See, e.g., Ex parte Liu and Zhao, Appeal 2009-015302, Application 10/820,647 (BPAI, 09/17/2010) (stating that "the Examiner has overemphasized the importance of working examples, and given 'too little credit to the abilities of a person having ordinary skill in the art" (citations omitted)) and Ex Parte Gante et al., Appeal No. 2000-0600, Application No. 08/642,268 (BPAI, 05/06/2002), (copies attached.)

There is, therefore, no reason to doubt that the enablement requirement of 35 U.S.C. § 112 is satisfied. Applicants respectfully request that the § 112 rejection be withdrawn.

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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